M E M O R A N D U M

Date: June 11, 2002

To: General and Plastic Surgery Devices Panel

From: Sam R. Arepalli, Ph.D.

Subject: Classification of the Scar Management Device

Inadvertently a few medical devices were not classified at the time of Medical Device Amendments of 1976 (the 1976 Amendments) to the Food, Drug and Cosmetic Act (the Act) (21 USC 360C). These medical devices are currently regulated as unclassified devices via premarket notification (510(k)).

The 1976 Amendments as amended by the Safe Medical Device Act (SMDA) of 1990 and the FDA Modernization Act (FDAMA) of 1997 provide regulations for the classification and regulation of medical devices intended for human use. FDA is required to classify all medical devices, including the remaining unclassified medical devices into the lowest regulatory class that can reasonably assure their safety and effectiveness for their intended use.

The Act established three categories (classes) of medical devices depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes are Class I (general controls), Class II (special controls), and Class III (pre-market approval). General controls are sufficient to provide reasonable assurance of the safety and effectiveness of Class I devices. General controls include the following: prohibition against adulterated or misbranded devices, premarket notification (510(k)), banned devices, the quality system regulation that includes design controls and good manufacturing processes (GMPs), registration of manufacturing facilities, listing of device types, record keeping, etc. Class II devices are those that cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such devices. These devices are regulated using special controls and general controls. Special controls include guidelines (guidance documents), performance standards, postmarket surveillance, clinical data, labeling, tracking requirements, and other appropriate actions the Secretary of the Department of Health and Human Services deems necessary to provide such assurance. Class III devices are those for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness. These devices are life sustaining, life supporting, or substantially important in preventing impairment of human health, or they present unreasonable risk of illness or

injury. Class III devices are regulated by using "valid scientific evidence" to establish the safety and effectiveness of the device. Valid scientific evidence includes well-controlled investigations, partially-controlled studies, uncontrolled studies, well-documented case histories, and reports of significant human experience.

When most device types were classified in the late 1970s and early 1980s, most Class I and Class II devices were cleared for marketing via the 510(k) process. Some Class I devices were also exempted from 510(k) clearance. Now many Class I devices and a few Class II devices are exempt from 510(k) clearance because their safety and effectiveness can be reasonably assured by other general controls, particularly by the quality system regulation general control. Examples of class I exempt products include hydrogel wound dressings, manual surgical instruments. Class II devices include implantable surgical meshes, sutures, dura mater substitute devices etc. Class III devices include Interactive Wound Dressings, Adhesion Barriers etc.

FDA has regulated silicone sheeting intended for scar management as an unclassified pre-amendment medical device. It has been cleared for marketing under several names, including silicone sheeting, silicone elastomer, and silicone gel for hypertrophic and keloid scar management. Also, the agency cleared a hydrogel for the same intended use.

Your panel package includes information on the classification of medical devices. Please note that some slides of the presentation in Tab 1b on Device Classification/ Reclassification Procedures have an asterisk (*). The asterisked slides pertain to the classification of unclassified preamendment devices and are relevant to the classification of the scar management device. Tab 1b also contains the questionnaire that you will vote on as part of your recommendation on the classification of this device. Tab 1c lists our panel discussion topics for the classification of this device. Tab 1d includes the only two medical device reports (MDR) on the device. Tab 1e is a bibliography of 13 articles on the clinical use of silicone sheeting and 1 article on the clinical use of a hydrogel for the intended use of scar management.

Risks to Health

FDA is proposing the following identification for the scar management device: A scar management device is a silicone sheeting product intended for use on uncompromised skin for scar management.

FDA regulates several silicone devices as Class III, Class II, Class I and unclassified devices. For example, the breast implant device, which has a silicone envelope and may contain a silicone gel filler is regulated as Class III medical device. Silicone chin, facial, etc. implants are regulated as Class II medical devices. Several other medical devices made of silicone are Class I devices and are exempt from 510(k) requirements (ex: drainage tubes). Silicone sheeting intended for the scar management is currently regulated as an unclassified medical device. Unlike the other silicone devices mentioned above, silicone sheeting intended for scar management is used on uncompromised skin.

FDA believes that the risk to health i.e., possible adverse skin reaction due to lack of biocompatibility exists.

FDA cleared about fifty pre-market notification (510(k)) applications for the scar management devices in the last five years. We searched medical device reports for the device adverse events. There are two adverse events reported (Tab 1e). The first adverse event was a significant blistering caused shortly after using gel sheeting followed by full thickness skin necrosis due to secondary infection. The blistering was not at the site of gel sheeting application, but in the areas nearby. It was determined by the reporting physician that the event was unrelated to the device but we could not rule out the possibility of the device involved. The other adverse event was severe red rash and flaky rough skin. This was determined as an isolated event and not likely that it was due to the use of the device.

The next page after this memorandum is a proposed regulatory identification for the scar management device.

_____ ____

Sam Arepalli, Ph.D. Date
FDA/CDRH/ODE/DGRND/PRSB